



Billing Code: 6750-01s

FEDERAL TRADE COMMISSION

[File No. 151 0129]

Mylan N.V.; Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent orders -- embodied in the consent agreement -- that would settle these allegations.

DATES: Comments must be received on or before December 3, 2015.

ADDRESSES: Interested parties may file a comment at

<https://ftcpublic.commentworks.com/ftc/mylanperrigoconsent> online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY**

INFORMATION section below. Write "Mylan N.V.- Consent Agreement, File No. 151-0129" on your comment and file your comment online at

<https://ftcpublic.commentworks.com/ftc/mylanperrigoconsent> by following the instructions on the web-based form. If you prefer to file your comment on paper, write "Mylan N.V.- Consent Agreement, File No. 151-0129" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center,

400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Jasmine Rosner (202-326-3558), Bureau of Competition, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for November 3, 2015), on the World Wide Web, at <http://www.ftc.gov/os/actions.shtm>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 3, 2015. Write “Mylan N.V.- Consent Agreement, File No. 151-0129” on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals’ home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone’s Social Security number, date of birth, driver’s license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card

number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any “[t]rade secret or any commercial or financial information which . . . is privileged or confidential,” as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).¹ Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/mylanperrigoconsent> by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#!home>, you also may file a comment through that website.

If you file your comment on paper, write “Mylan N.V.- Consent Agreement, File No. 151-0129” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW,

¹ In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 3, 2015. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

Analysis of Agreement Containing Consent Orders to Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Mylan N.V. ("Mylan") that is designed to remedy the anticompetitive effects resulting from Mylan's acquisition of Perrigo Company plc ("Perrigo"). Under the terms of the proposed Consent Agreement, Mylan is required to divest to Alvogen, Inc. ("Alvogen") all of its rights and assets to the following generic pharmaceutical products: (1) acyclovir ointment; (2) bromocriptine mesylate tablets; (3) clindamycin phosphate/benzoyl peroxide gel; (4) hydromorphone hydrochloride extended release tablets; (5) liothyronine sodium tablets; (6) polyethylene glycol 3350 over-the-counter ("OTC") oral solution packets; and (7) scopolamine extended release transdermal patches.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the

proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision and Order (“Order”).

On September 14, 2015, Mylan launched a hostile tender offer to gain a controlling interest in Perrigo. The Commission alleges in its Complaint that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening current and future competition in seven generic pharmaceutical markets in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

I. The Products and Structure of the Markets

A generic pharmaceutical drug contains the same active ingredient as the brand name product, but typically at a much more affordable price. Pharmaceutical companies usually launch generic versions of drugs after a branded product loses its patent protection. When only one generic product is available, the price for the branded product typically acts as a ceiling above which the generic manufacturer cannot price its product. During this period, the branded product competes directly with the generic. Once multiple generic suppliers enter a market, the branded drug manufacturer usually ceases to provide any competitive constraint on the prices for generic versions of the drug. Rather, generic suppliers compete only against each other.

Mylan’s proposed acquisition of Perrigo will lessen competition in seven concentrated generic pharmaceutical product markets by reducing the number of current or future suppliers competing in each market. The proposed acquisition will reduce current competition in four

generic pharmaceutical markets: (1) bromocriptine mesylate tablets; (2) clindamycin phosphate/benzoyl peroxide gel; (3) liothyronine sodium tablets; and (4) polyethylene glycol 3350 OTC oral solution packets.

- Bromocriptine mesylate is a dopamine agonist used to treat Type 2 diabetes, pituitary tumors, Parkinson's disease, neuroleptic malignant syndrome, and hyperprolactinemia. The market for generic 2.5 mg bromocriptine mesylate tablets is highly concentrated with only three current suppliers: Mylan, Perrigo, and Sandoz AG. Absent a remedy, the proposed transaction would consolidate the market from three to two suppliers.
- Clindamycin phosphate/benzoyl peroxide gel is a combination antibiotic and drying agent used to stop the bacterial infection that causes acne. Today, only Mylan supplies the market with generic clindamycin phosphate 1%/benzoyl peroxide 5% gel. Perrigo recently received FDA approval for generic clindamycin phosphate 1%/benzoyl peroxide 5% gel and is poised to start supplying the market in the near future. As a result, the proposed transaction would reduce the number of generic clindamycin phosphate 1%/benzoyl peroxide 5% gel suppliers from two to one.
- Liothyronine sodium is a synthetic thyroid hormone used to treat hypothyroidism and to treat or prevent enlarged thyroid glands. Currently, only three suppliers provide generic liothyronine sodium tablets in the 0.005 mg, 0.025 mg, and 0.05 mg strengths: Mylan, Perrigo, and SigmaPharm Laboratories, LLC. The proposed transaction would further consolidate an already highly concentrated market, leaving two suppliers post-transaction.

- Polyethylene glycol 3350, a laxative, is an OTC oral solution packet used to treat occasional constipation. In the 17 gm/packet OTC market, Mylan, Perrigo, and Gavis Pharmaceuticals, LLC, are the only active suppliers in the market. As a result, the proposed transaction would consolidate the number of active suppliers of generic polyethylene glycol 3350 OTC oral solution packets from three to two.

Additionally, the proposed acquisition will reduce future competition in three generic pharmaceutical markets: (1) acyclovir ointment; (2) hydromorphone hydrochloride extended release tablets; and (3) scopolamine extended release transdermal patches. In each of these markets, either Mylan or Perrigo is a likely new entrant in the near future. Without a remedy, the proposed acquisition would eliminate an independent entrant into each market, likely depriving customers of the significant cost savings that result when an additional generic supplier enters a concentrated market.

- Acyclovir ointment is a topical product used to slow the growth and spread of the herpes virus. Mylan and Amneal Pharmaceuticals LLC currently hold ANDAs and supply acyclovir 5% ointment. Allergan plc (“Allergan”) also sells an authorized generic version of acyclovir 5% ointment. Perrigo is one of a limited number of suppliers likely to enter this market in the near future.
- Hydromorphone hydrochloride is an analgesic used to treat moderate to severe pain in narcotic-tolerant patients. Perrigo and Allergan hold ANDAs for 8 mg, 12 mg, and 16 mg extended release tablets. In addition, Mallinckrodt plc markets an authorized generic version of hydromorphone hydrochloride extended release tablets. Mylan is one of a limited number of suppliers likely to enter this market in the near future.

- Scopolamine transdermal patches prevent nausea and vomiting associated with motion sickness and recovery from anesthesia and surgery. Novartis AG currently markets the branded version, Transderm Scop, which is available as a 1 mg/72 hour extended release transdermal patch. Perrigo holds the only approved ANDA for the generic version of Transderm Scop. Mylan is one of a limited number of other suppliers likely to enter this market in the near future. As there is no generic version of Transderm Scop on the market today, it is likely that the price for scopolamine transdermal patches would significantly decrease with the onset of generic competition. Without a remedy, the proposed acquisition would eliminate the price reductions that would likely have accompanied Mylan's independent entry into this market.

II. Entry

Entry into each of these generic pharmaceutical markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration ("FDA"), is costly and lengthy.

III. Effects

The proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating current or future competition between Mylan and Perrigo in these seven concentrated markets. In each of these markets, Mylan and Perrigo are two of a limited number of current or likely future suppliers in the United States. Market participants characterize each of the markets as a current or likely future commodity market, in which the number of generic suppliers has a direct impact on pricing. Customers and competitors have

observed that the price of generic pharmaceutical products decreases with new entry even after several suppliers have entered the market. Removal of an independent generic pharmaceutical supplier from the relevant markets in which Mylan and Perrigo currently compete likely would result in significantly higher prices post-acquisition. Similarly, the elimination of a future independent competitor would prevent the price decreases that are likely to result from the firm's entry. Thus, absent a remedy, the proposed acquisition will likely cause U.S. consumers to pay significantly higher prices for these generic drugs.

IV. The Consent Agreement

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in each relevant market. Under the Consent Agreement, Mylan is required to divest to Alvogen its rights to the seven relevant products. Alvogen is an international pharmaceutical company, with commercial operations in thirty-four countries. Its business focuses on developing, manufacturing, and distributing generic, branded, and OTC pharmaceutical products. Mylan must accomplish the divestitures to Alvogen and relinquish its rights to these products no later than thirty days after the proposed acquisition is consummated.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that Alvogen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Mylan to unwind the sale of rights to Alvogen and to divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee if Mylan fails to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Mylan to take all action to maintain the economic viability, marketability, and competitiveness of the products to be divested until such time that they are transferred to a Commission-approved acquirer. Mylan must provide transitional services to Alvogen to assist it in establishing independent manufacturing capabilities. These transitional services include technical assistance to manufacture the divestiture products in substantially the same manner and quality employed or achieved by Mylan, and advice and training from knowledgeable Mylan employees. Mylan must also provide Alvogen with a supply of the divested products while Mylan transfers manufacturing technology to Alvogen or its designated manufacturer. The goal of the transitional services is to ensure that Alvogen will be able to operate independent of Mylan in the manufacture and sale of the divested products. Nothing in the Consent Agreement, however, precludes Alvogen from sourcing active pharmaceutical ingredients or other divestiture product inputs from Mylan on a negotiated basis.

As Alvogen was unable to perform due diligence on the Perrigo products at issue, Mylan divested its own on-market, generic acyclovir ointment product rather than Perrigo's product in development. Because the competition that is preserved by the proposed Consent Agreement will only occur when the Perrigo product is launched, the proposed Order permits Mylan to retain the right to sell acyclovir ointment through a license from Alvogen until thirty days after Mylan receives approval for the Perrigo ANDA, but for no longer than three years. This provision is designed to permit Mylan to remain an active market participant pending the approval of Perrigo's acyclovir ointment ANDA but also ensures Mylan's continued incentive to develop and launch the Perrigo product.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

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